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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,915	08/15/2001	Ashley J. Birkett	ICC-102.2US 81175	2278
24628	7590	10/29/2007	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			PENG, BO	
			ART UNIT	PAPER NUMBER
			1648	
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			10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/930,915

Applicant(s)

BIRKETT, ASHLEY J.

Examiner

Bo Peng

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-33, 35-38 and 42-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-33, 35-38 and 42-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

1. This Office Action is in response to the amendment filed August 21, 2007. Claims 1-9, 12-33, 35-38 and 42-78 are pending, and are under consideration in this Office action.

Claim Rejections - 35 USC § 112, first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of Claims 18-38 and 42-78 under 35 U.S.C. 112, first paragraph, for introduction of new matter, **is withdrawn** in view of the deletion of the new matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of Claims 1-9, 15, 16, 18-26, 30-33, 35, 38, 42-58, 63-75, 77 and 78 under 35 U.S.C. 103(a), as being unpatentable over Pumpens et al. (1995) in view of Zlotnick et al (1997), **is maintained**.

Art Unit: 1648

6. Applicant argues again that Ulrich, as ordinary skill in the art, who stated that the stability problem of HBc was not solved, did not suggest that the desired stability could be achieved by combining teachings of both Pumpens and Zlotnick, but rather maintained that the problem still had to be solved.

7. The response to this argument was set forth in the previous Office action (See Para 11 and 12).

8. Applicant further argues that Zlotnick's Cp*150, which is an HBc Δ containing a cystine at its C-termini, is not stable.

9. In response to Applicant's argument, all structure limitations of the instant claims contain such structural features taught or suggested by Pumpens and Zlotnick. Applicant has not explicitly pointed out what are the specific structural features of the alleged HBc chimera that are different from those of the prior art, which contribute alleged enhanced stability of the claimed HBc chimera.

10. It is noted that Applicant has amended Claims 1, 18, 42, 51 and 63 as recited: "wherein said particle stability is assayed as a measurement of the percentage of full length chimera molecules determined by Coomassie Blue stain of reducing buffer 15%SDS-PAGE results obtained after dilution of purified particles to a concentration of 1 mg/mL in aqueous 50 mM NAP04, pH 6.8, with sodium azide added to a final concentration of 0.02% and incubation at 37°C for about 14 days."

11. However, the amendment does not constitute a structural or functional limitation to the alleged HBc chimera because the amendment is directed to a method of measuring an HBc particle, which does not change the structural or functional characteristics of the alleged chimera

Art Unit: 1648

HBc. Thus, the rejection is maintained.

12. The rejection of Claims 12-14, 17, 27-29, 36, 37, 59-62 and 76 under 35 U.S.C. 103(a), as being unpatentable over Pumpens et al. (1995), in view of Zlotnick et al (1997) as applied to Claims 1-9, 15, 16, 18-26, 30-33, 35, 38, 42-58, 63-75, 77 and 78, further in view of Thornton et al. (US 5,143,726) **is maintained** for the same reasons of record.

13. Applicant argues that the instant claims recite directly or indirectly that the chimeric molecule "contains a heterologous linker residue for a conjugated epitope". Thornton teaches only amino acid side chains that are endogenously present. As such, the skilled worker who did not have the present application in front of him or her would have to alter the sequence of the immunogenic loop with no guidance for doing so.

14. Applicant's argument is not convincing because the invention as a whole is obvious since it is within one of skill in the art to either introduce a heterologous linker, or utilize specific amino acids as linker residues, for a conjugated epitope. Thornton teaches that methods for operatively linking individual polypeptides through an amino acid residue side chain to form an immunogenic conjugate, i.e., a branched-chain polypeptide polymer, are well known in the art (Line 13-45, column 10). Useful side chain functional groups include epsilon-amino groups, beta- or gamma-carboxyl groups, thiol (--SH) groups and aromatic rings (e.g. **tyrosine** and **histidine**). Furthermore, Thornton teaches that, as is well known in the art, both the HBcAg protein and polypeptide immunogen can be used in their native form or their functional group content may be modified by succinylation of **lysine** residues or reaction with **cysteine**-thiolactone. The polypeptides can also be modified to incorporate spacer arms, such as hexamethylene diamine or other bifunctional molecules of similar size, to facilitate linking (Line

Art Unit: 1648

13-45, column 10).

15. Since it is within one of skill in the art to either introduce a heterologous peptides into HBc, or utilize specific amino acids, such as lysine and cysteine, as linker residues for a conjugated epitope, it is within one of skill in the art to introduce a heterologous linker for a conjugated epitope by some technique taught by Pumpens and Thornton. Therefore, the rejection is maintained.

Remarks

16. No claim is allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1648

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bo Peng, Ph.D.
October 16, 2007

A handwritten signature in black ink, reading "Bruce Campell". The signature is written in a cursive, flowing style.

BRUCE R. CAMPELL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600